DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

October 12, 1999

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-06

Don Giles, President
Icicle Seafoods, Inc.
4019 21st Avenue West
Seattle, Washington 98199

WARNING LETTER

Dear Mr. Giles:

On August 7 and 8, 1999, the Food and Drug Administration (FDA) conducted an inspection of your plant located at Petersburg Fisheries, 411 N. Nordic, Petersburg, Alaska. At the conclusion of the inspection, Katherine L. Reischling was presented with a Form FDA 483 listing serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (HACCP Regulation). A copy of that Form FDA 483 is enclosed for your review. By virtue of these deficiencies, all species of whole cooked crab processed by your firm are adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) and 21 CFR Part 123.

1. Your HACCP plan for all species of whole cooked crab does not identify the food safety hazards that are being controlled in your process. Natural toxins at the receiving step and pathogen survival in the cook step are food safety hazards that are reasonably likely to occur in your process. 21 CFR Part 123.6(c)(1) requires you to list the food safety hazards that are reasonably likely to occur. A hazard analysis, as defined in 21 CFR Part 123.6(a), is conducted to determine whether there are food safety hazards that are reasonably likely to occur in your product and identify preventive measures to control those hazards. The hazard analysis is not considered part of the mandatory written HACCP plan.

2. Your HACCP plan for all species of whole cooked crab does not identify the processing steps for critical control point 1 (CCP1) and critical control point 2 (CCP2). It was explained to our investigators that CCP1 and CCP2 are associated with the specific processing steps of receiving and holding, respectively. It was further explained that these steps are identified in the hazard review analysis for this product. 21 CFR Part 123.6(c)(2) requires you to list the critical control points for each identified food safety hazard as part of your HACCP plan.

3. The frequency of monitoring is not listed for CCP1 and CCP2 in your HACCP plan. 21 CFR Part 123.6(c)(4) requires you to list the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits. You stated that ADEC monitors the assigned statistical areas of harvest, and that frequency is determined by them. A statement in your HACCP plan to better explain this strategy is suggested.

Our investigators also felt that the monitoring procedures and records are not consistent with the critical limits for CCP1 and CCP2. Our investigators stated, that although your procedure to control the hazard of natural toxins is likely adequate, your HACCP plan is confusing as written. Rather than listing values for critical limits, which implies testing by your firm, actual written statements as to ADEC practices under certain conditions, would be a less confusing approach.

4. Verification procedures in your HACCP plan at CCP1 and CCP2 do not include record review. 21 CFR Part 123.6(c)(6) requires you to list the verification procedures, and frequency thereof, that a processor will use in accordance with 21 CFR Part 123.8(a)(3), *Records review.*

5. Your HACCP plan does not reflect actual procedures taken in monitoring the cook step as a critical control point in your process. 21 CFR Part 123.6(c)(4) requires you to list the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits. Your HACCP plan should reflect actual practices taking place during your process.

6. Verification procedures in the cook step of your HACCP plan do not specify the frequency of record review and thermometer calibration. 21 CFR Part 123.6(c)(6) requires you to list the verification procedures, and frequency thereof, that a processor will use in accordance with 21 CFR Part 123.8(a)(3)(i), *Records review*, and 21 CFR Part 123.8(a)(2)(ii), *On going verification activities.*

During the previous inspection, on August 11 and 12, 1998, and in a letter from the FDA, dated February 2, 1999, you were notified of the same deficiencies described in points numbered 1 through 6 of this letter. During the inspection, and in the letter, the FDA explained that you would need to take steps to correct those deficiencies. The FDA is concerned that in fourteen months time your firm has not taken action to correct these deficiencies.

The above HACCP violations are not meant to be an all-inclusive list of deficiencies in your plant. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. You should take prompt action to correct all of the violations noted in this letter. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay, and the time within which the corrections will be completed. Pertinent sections of the Act and the Regulations are enclosed for your review. Your reply relating to these concerns should be addressed to the Food and Drug Administration, Attention: Diane J. Englund, Acting Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421.

Sincerely,

Kristy D. Ruiz

for Austin R. Long, Ph.D.
Acting District Director

Enclosures:
Form FDA 483
21 CFR PART 123
Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: ADEC with disclosure statement